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Appendices

510(k) Summary of Safety and Effectiveness (App. A)

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device description

The ENDOPATH® EZ-RF Linear Cutter and Coagulation device:

- delivers a line of bipolar coagulation
- followed by two double-staggered rows of staples
- while simultaneously dividing the tissue.

A safety lockout feature is incorporated into the cartridge. The line of bipolar coagulation delivered is approximately 37mm long with a 37mm staple line length, and a cut length of 35mm. A staple retaining cap on the cartridge protects the staples during shipping and transportation. The instrument is reloadable with a universal cartridge and is acceptable for use on tissue which can be compressed to a thickness of 2.0mm or less. The instrument is designed to be reloaded seven times for a maximum of eight firings per instrument.

The ENDOPATH® EZ-RF Linear Cutter and Coagulation device is designed to have an integral Indicator Light on the Linear Cutter or an external Indicator Light device. The Linear Cutter connects to an RF electrosurgical generator with an integrated cord from the Linear Cutter to the generator or the external Indicator Light device. The Indicator Light device illuminates when current is flowing above a reference current threshold.

Specific generators for use with this instrument include the ERBE ERBOTOM ICC 350 and Valleylab Force 2 electrosurgical generators (see Appendix G). New generators will be added to the labeling as they pass the appropriate qualifications. Any specific instructions/details for use with additional ESG's will also be added to the labeling.

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510(k) Summary of Safety and Effectiveness, Continued

Intended use	For coagulation, transection, and resection of tissue.
Indications statement	The ENDOPATH® EZ-RF Linear Cutter and Coagulation device has applications in open and minimally invasive surgical procedures for coagulation, transection, and resection of tissue. The bipolar feature is to be used only with the ERBE ERBOTOM ICC 350 or the Valleylab Force 2 electrosurgical generators.
Technological characteristics	The technological characteristics of the New Device are the same as the ELC and Forceps Predicate Device.
Performance data	Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. The studies demonstrated acceptable performance in coagulation, transection, and resection of tissue.
Conclusion	Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the New Device is substantially equivalent to the ELC and Forceps Predicate Devices under the Federal Food, Drug and Cosmetic Act.
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